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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: KONGERSLEV=1

In re Application of:)	Confirmation No.: 6668
Leif KONGERSLEV)	
)	Art Unit:
)	
Appln. No.: 10/820,155)	Examiner:
)	
Filed: April 8, 2004)	Washington, D.C.
)	
For: TREATMENT OF SARS IN)	October 6, 2004
INDIVIDUALS)	

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop Missing Parts
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

(Check one of the boxes A-D)

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

☒ B. before the mailing date of a first Office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

(Check one of the boxes "i" and "ii" below:)

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following)

☐ ii. A check (check no. _____) for the fee set forth in §1.17(p), presently believed to be \$180, is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) state as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein was either

(Check one of the boxes "a" and "b" below)

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following and this note) A check (check no. _____) for/ Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be \$180 is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., Form PTO/SB/08A) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate)

☐ A. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with §1.98(c), only a copy of each of the latter documents is enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications)

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 (or PTO/SB/08A) from the files of the prior application(s) or a fresh PTO-1449 (or PTO/SB/08A) listing these documents, and request that they be considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

☐ C. Document(s) _____ is (are) U.S. patent(s) and/or published application(s). As this is a U.S. application filed after June 30, 2003, or an entry into national stage under 35 USC §371 after June 30, 2003, the requirement to file copies of such U.S. patents or published applications has been waived. (Office of Patent Legal Administration - Pre O.G. Notice of July 11, 2003).

3. Document _____ is (are) not in the English language. In accordance with §1.98(c), Applicant(s) states:

[] An English translation of each document _____ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

[] A concise explanation of the relevance of document(s) _____ is found in the attached _____ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of document(s) _____ is set forth as follows:

(insert concise explanation of relevance)

[] A concise explanation of the relevance of document _____ can be found on page 1 of the specification.

[] A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. Other information being provided for the examiner's consideration follows:

(insert other information)

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56

In re Appln. No. 10/820,155

(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/820,155
Filing Date	April 8, 2004
First Named Inventor	Leif KONGERSLEV
Group Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	KONGERSLEV

Sheet 1 of 2

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
AA		Aittoniemi, J., Miettinen, A., Laine, S., Sinisalo, M., Laippala, P., Vilpo, L., Vilpo, J. (1999), Opsonising immunoglobulins and mannan-binding lectin in chronic lymphocytic leukemia, <u>Leuk Lymphoma</u> Jul;34(34):3815	
AB		Christiansen, O.B., Kilpatrick, D.C., Souter, V., Varming, K., Thiel, S., Jensenius, J.C. (1999) Mannan-binding lectin deficiency is associated with unexplained recurrent miscarriage. <u>Scand. J. Immunol.</u> , 49, 193-196	
AC		van Emmerik, LC, Kuijper, EJ, Fijen, CAP, Dankert, J, and Thiel, S (1994) Binding of mannan-binding protein to various bacterial pathogens of meningitis. <u>Clin.Exp.Immunol.</u> 97:411-416.	
AD		Fischer, PB, Ellerman-Eriksen, S, Thiel, S, Jensenius, JC, and Mogensen, SC (1994) Mannan-binding protein and conglutinin mediate enhancement of herpes simplex virus type-2 infection in mice. <u>Scand J Immunol</u> 39:439-445.	
AE		Garred, P, Harboe, M, Oettinger, T, Koch, C, and Svejgaard, A (1994) Dual role of mannanbinding protein in infections: Another case of heterosis? <u>Eur.J.Immunogen.</u> 21:125-131.	
AF		Garred P, Madsen HO, Hofmann B and Svejgaard A (1995) Increased frequency of homozygosity of abnormal mannan binding protein alleles in patients with suspected immunodeficiency. <u>Lancet</u> , 346: 941-943	
AG		Hoal-Van Helden EG, Epstein J, Victor TC, Hon D, Lewis LA, Beyers N, Zurakowski D, Ezekowitz AB, Van Helden PD (1999) Mannose-binding protein B allele confers protection against tuberculous meningitis. <u>Pediatr Res</u> 45:459-64	
AH		Holmskov, U., Malhotra, R., Sim, R.B., and Jensenius, J.C. (1994) Collectins: collagenous C-type lectins of the innate immune defense system. <u>Immunol.Today</u> 15:67-74.	
AI		Holmskov, U., Thiel, S., Jensenius, J.C. (2003) Collectins and ficolins: Humoral lectins of the innate immune defense. <u>Annu. Rev. Immunol.</u> 21:547-578.	
AJ		Jack DL, Dodds AW, Anwar N, Ison CA, Law A, Frosch M, Turner MW and Klein NJ (1998) Activation of complement by Mannose-binding lectin on isogenic mutants of <i>Neisseria meningitidis</i> serogroup B. <u>J Immunol</u> 160: 1346-1353	
AK		Janeway CA, Travers P, Walport M and Capra JD (1999) Immunobiology, the immune system in health and disease, <u>Immunobiol</u> , Fourth Edition, Churchill Livingstone.	
AL		Kilpatrick, D.C. (2002) Mannan-binding lectin: clinical significance and applications. <u>Biochim. Biophys. Acta</u> 1572:401-413. Turner, M.W. (1996) Mannose-binding lectin: the pluripotent molecule of the innate immune system. <u>Immunol.Today</u> 17:532-540.	
AM		Lehrnbecher T, Venzon D, de Haas M, Chanock SJ, Kuhl J. (1999) Assessment of measuring circulating levels of interleukin6, interleukin8, Creactive protein, soluble Fc gamma receptor type III, and mannosebinding protein in febrile children with cancer and neutropenia. <u>Clin Infect Dis</u> , Aug;29(2):4149.	
AN		Lipscombe, R.J., Sumiya, M., Summerfield, J.A. & M.W. Turner (1995) Distinct physicochemical characteristics of human mannose-binding protein expressed by individuals of differing genotype. <u>Immunology</u> 85:660-667.	
AO		Lu, J., Thiel, S., Wiedemann, H., Timpl, R. & K.B.M. Reid (1990) Binding of the pentamer/hexamer forms of mannan-binding protein to zymosan activates the proenzyme C1r ₂ C1s ₂ complex, of the classical pathway of complement without involvement of C1q. <u>J. Immunol.</u> 144:2287-2294.	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

AP	Madsen, H.O., Garred, P., Kurtzhals, J.A., Lamm, L.U., Ryder, L.P., Thiel, S., and Svejgaard, A. (1994) A new frequent allele is the missing link in the structural polymorphism of the human mannan-binding protein. <u>Immunogenetics</u> 40:37-44.	
AQ	Matsushita, M. and Fujita, T (1992). Activation of the classical complement pathway by mannose-binding protein in association with a novel C1s-like serine protease. <u>J.Exp.Med.</u> 176:1497-1502.	
AR	Miller, M.E., Seals, J., Kaye, R., and Levitsky, L.C. (1968) A familial, plasma-associated defect of phagocytosis. A new case of recurrent bacterial infections. <u>The Lancet</u> :60-63.	
AS	Nielsen, S.L., Andersen, P.L., Koch, C., Jensenius, J.C., and Thiel, S. (1995) The level of the serum opsonin, mannan-binding protein in HIV-1 antibody-positive patients. <u>Clin. Exp. Immunol.</u> 100:219-222.	
AT	Pizzo, PA (1993), Management of fever in patients with cancer and treatment-induced neutropenia, <u>N Eng J Med</u> , 328, 1323-1332.	
AU	Sastry, K., Herman, G.A., Day, L., Deignan, E., Bruns, G., Morton, C.C. & R.A.B. Ezekowitz (1989) The human mannose-binding protein gene. <u>J. Exp. Med.</u> 170:1175-1189	
AV	Stover CM, Thiel S, Thelen M, Lynch NJ, Vorup-Jensen T, Jensenius JC and Schwaebler WJ (1999) Two constituents of the initiation complex of the mannan-binding lectin activation pathway of complement are encoded by a single structure gene. <u>J Immunol</u> 162: 3481-3490	
AW	Summerfield JA, Ryder S, Sumiya M, Thursz M, Gorchein A, Monteil MA and Turner MW (1995) Mannose binding protein gene mutations associated with unusual and severe infections in adults. <u>Lancet</u> 345: 886-889	
AX	Summerfield JA, Sumiya M, Levin M and Turner MW (1997) Association of mutations in mannose-binding protein gene with childhood infection in consecutive hospital series. <u>BioMed J</u> 314: 1229-1232	
AY	Super, M., Thiel, S., Lu, J., Levinsky, R.J., and Turner, M.W. (1989) Association of low levels of mannan-binding protein with a common defect of opsonisation. <u>Lancet</u> 2:1236-1239.	
AZ	Thiel S, Vorup-Jensen T, Stover CM, Schwaebler W, Laursen SB, Poulsen K, Willis AC, Eggleston P, Hansen S, Holmskov U, Reid KB and Jensenius JC (1997) A second serine protease associated with mannan-binding lectin that activates complement. <u>Nature</u> , 386(6624): 506-510	
BA	Thiel S, Holmskov U, Hviid L, Laursen SB and Jensenius JC (1992) The concentration of the C-type lectin, mannan-binding protein, in human plasma increases during an acute phase response. <u>Clin Exp Immunol</u> 90: 31-35	
BB	Turner, M.W. (1996) Mannose-binding lectin: the pluripotent molecule of the innate immune system. <u>Immunol Today</u> 17:532-540.	
BC	Valdimarsson H, Stefansson M, Vikingsdottir T, Arason GJ, Koch C, Thiel S and Jensenius JC (1998) Reconstitution of opsonizing activity by infusion of mannan-binding lectin (MBL) to MBL-deficient humans. <u>Scand Journal of Immunology</u> 48:116-123.	
BD	Weis WI, Taylor ME and Drickamer K (1998) The C-type lectin superfamily in the immune system. <u>Immunological Reviews</u> 163: 19-34	

Examiner Signature		Date Considered	
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.